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Re: Patent Term Extension
Application for
U.S. Patent No. 4,219,478

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,219,478 issued August 26, 1980, which claims the human drug product Mycobutin, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 1,406 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of April 15, 1994, as amended on June 14, 1994. Under 35 USC § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (2,127) + 342 \\ &= 1,406 \text{ days}\end{aligned}$$

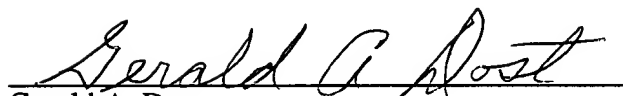
Since the regulatory review period began after the patent issue date, the entire period has been considered in the above calculation. No determination of a lack of due diligence was made.

The limitation of 35 USC § 156(g)(6) and the 14 year exception of 35 USC § 156(c)(3) do not operate to reduce the period determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,219,478 a certificate of extension, under seal, for a period of 1,406 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,219,478
Granted:	August 26, 1980
Applicant:	Leonardo Marsili et al.
Owner of Record:	Farmitalia Carlo Erba S.r.l.
Title:	RIFAMYCIN COMPOUNDS
Classification:	540/453
Product Trade Name:	Mycobutin
Term Extended:	1,406 days


Gerald A. Dost
Special Program Examiner
Office of Special Programs
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9282

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Mycobutin

FDA Docket No.: 93E - 0099